JAN - 8 2001

K003151

MARTIN URAM, M.D.

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225 East 64th Street
New York, New York 10021
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510 (k) Summary For The URAM MW MH MicroProbe Laser & Endoscopy System

1. - Date Summary Prepared:

October 6, 2000

2. - Submitter's Name and Address:

Martin Uram, MD

39 Sycamore Avenue

Little Silver, NJ 07739-1208

Contact Person: Keith Hertz

Tel.: (732) 530-6762 Fax: (732) 530-5344

E-mail: info@endo-optiks.com

3. - Device Name:

Trade / Proprietary Name:	URAM MW MH MicroProbe Laser
Common Name:	Surgical Laser System
Classification Name:	Surgical Laser

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510 (k) Summary For The URAM MW MH MicroProbe Laser & Endoscopy System

4. - Predicate Devices:

The legally marketed devices to which equivalence is being claimed are:

Uram Opthalmic Laser Endoscope

Family of Endoscopes

Endo Optiks Multi-wavelength E3 MicroProbe

Pentax Metal Halide Light Sources

MedCam Technology Metal Halide Light Sources

Escalon Trek Medical Products Light Sources

5. - Device Description:

The Endo Optiks URAM MW MH MicroProbe consists of a laser and endoscopy system.

The URAM MW MH MicroProbe is a modification of the previously cleared device except that a metal halide light source is substituted for xenon.

Labeling The E3 Multi-wavelength MicroProbe will be renamed (relabeled) the URAM MW MH MicroProbe.

New Feature Metal halide lamps have a brighter whiter light that can be focused with extreme precision into a fiber optic cable. The result is higher efficiency of light energy coupled into the fiber optic bundle -- leading to brighter, crisper images. Illumination appears white, similar to that of daylight. There is no other change in construction or performance of this device.

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510 (k) Summary For The URAM MW MH MicroProbe Laser & Endoscopy System

Indication For Use: In conjunction with endoscopy, the indications include both contact and non-contact ablation, incision, excision, coagulation and vaporization for the following soft tissue applications:

- General Surgery
- Ophthalmology / Oculoplastic
- Urology
- Gastroenterology
- Gynecology
- Otorhinolaryngology
- Pulmonary / Thoracic
- Dermatology / Plastic Surgery
- Orthopedic
- Neurosurgery – hemostasis only

6. - Intended Use:

The URAM MW MH MicroProbe provides simultaneous imaging, illumination, and laser delivery through various endoscopes.

7. - Comparison of Technological Characteristics

This modification substitutes a metal halide light source in place of xenon (as used in the predicate device).

8. - Nonclinical Tests Used in Determination of Substancial Equivalence

The design of the URAM MW MH MicroProbe has been thoroughly validated at the unit and system level. The tests showed that all system specifications are satisfied.

9. - Conclusions From Nonclinical Testing

The testing of the modified devices demonstrates that the performance is substantially equivalent to the predicate prior to the modifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 2001

Mr. Keith Hertz
Regulatory Affairs
Endo Optiks, Inc.
39 Sycamore Avenue
Little Silver, New Jersey 07739

Re: K003151
Trade Name: URAM MWMH MicroProbe Surgical Laser System and Endoscopy
Regulatory Class: II
Product Code: GEX
Dated: October 6, 2000
Received: October 10, 2000

Dear Mr. Hertz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Rovot for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510 k Number: K 003151

Device Name: ~~URAM MWMH~~ MicroProbe
Surgical Laser System and Endoscopy

Indications For Use

Endoscopic and laser surgery with contact and non-contact excision, hemostasis, incision, vaporization and ablation for the following soft tissue applications:

General Surgery
Ophthalmology / Oculoplastic
Urology
Gastroenterology
Gynecology
Otorhinolaryngology
Pulmonary / Thoracic
Dermatology / Plastic Surgery
Orthopedic

Neurosurgery - hemostasis only

Concurrent of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003151